

Notice of Allowability

Application No.

09/825,105

Examiner

Q. Janice Li

Applicant(s)

RUSSELL ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/8/04 response.
2. ☒ The allowed claim(s) is/are 1-3,6 and 24-29.
3. ☒ The drawings filed on 03 April 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

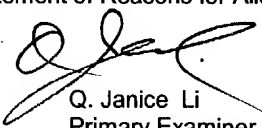
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Q. Janice Li
Primary Examiner
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DETAILED ACTION

The amendment and response filed 6/8/04 have been entered. Claims 1, 6, 24, and 27 have been amended. Claims 1-3, 6, and 24-29 are pending in the application and under current examination. Previous rejections are withdrawn in view of the amendment, arguments, and the following Examiner's amendment.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Benjamin A. Adler on September 3, 2004.

The claims have been amended as follows:

Claim 1. (currently amended) A method of inducing an immune response by ~~administration of,~~ wherein the method comprises administering mucosally to a subject a recombinant immunogen comprising a fusion protein containing a heterologous ~~of an~~ antigen of interest fused to the A2 and B subunits of a type II heat-labile enterotoxin.

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Claim 24. (currently amended) A method of increasing Th1 response and cell-mediated immunity ~~by administration of,~~ wherein the method comprises administering mucosally to a subject a recombinant immunogen comprising a fusion protein containing a heterologous ~~of an~~ antigen of interest fused to the A2 and B subunits of a type II heat-labile enterotoxin.

In claim 26, “intramuscularly, transcutaneously and subcutaneously” were deleted.

Claim 27. (currently amended) A method of increasing Th1 response and cell-mediated immunity ~~by administration of,~~ wherein the method comprises administering mucosally to a subject a recombinant immunogen comprising a fusion protein containing a heterologous ~~of an~~ antigen of interest fused to the A2 and B subunits of a *E. Coli* heat-labile enterotoxin.

In claim 29, “intramuscularly, transcutaneously and subcutaneously” were deleted.

Conclusion

Claims 1-3, 6, and 24-29 are allowed.

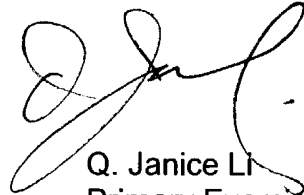
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730.

The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **703-308-0196**.



Q. Janice Li
Primary Examiner
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September 7, 2004

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